

REMARKS

It is respectfully requested that this application be reconsidered in view of the following remarks and that all of the claims in this application be allowed.

Examiner Interview

The undersigned wishes to thank Examiners Arnold and Qazi for the courtesies extended during the personal interview conducted on June 14, 2006 for this application. The Interview Summary provided accurately summarizes the issues discussed some of which are elaborated upon below.

Election of Species Requirement

Claims 1-22 were subject to an election of species requirement in the Office Action of December 12, 2005. In response, Applicant elected as its single disclosed species "primary pulmonary hypertension".

In view of this election and in view of the rejection repeated below, Claims 21 and 22 are withdrawn from consideration as being directed to a non-elected species.

Drawings

The Examiner objects to the figure because the drawing was blurry and hard to read. Attached hereto is a Replacement Sheet of Figure 1 in compliance with 37 CFR 1.121(d), correcting the deficiencies identified by the Examiner. No new matter was added by the replacement figure. Applicant requests withdrawal of this objection.

Rejection under 35 U.S.C. §103(a)

Claims 1-20 stand rejected under 35 U.S.C. §103(a) over Smith, et al., U.S. Patent Application Publication No. 2002/0051766 (now US Patent No. 6,572,895) in view of Sakai, et al., JACC 1996 28(6), 1580-1588, and Cooke, et al., International Angiology, 1997, 16(4), 250-254. For the following reason, this rejection is traversed.

The test for non-obviousness was articulated by the Court of Appeals for the Federal Circuit in *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). *Vaeck* requires consideration of at least the following factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should practice the claimed invention; and (2) whether the prior art would also have provided a reasonable expectation of success to such a skilled artisan.

The first requirement goes to the question of motivation, and refers to a line of well established cases that there must be some logical reason at the time of the invention for modifying the cited references along the lines of the invention; otherwise the use of the teachings as evidence of non-obviousness will entail prohibited hindsight. *Ex parte Stauber and Eberle*, 208 USPQ 945 (Bd. App., 1980).

In the present case, this rejection is maintained because the teachings of Smith relating to treatment of congestive heart failure (CHF) allegedly would suggest the claimed invention when combined with Sakai and Cooke particularly in view of Sakai's teaching that congestive heart failure accompanies pulmonary hypertension. Applicants take issue with this allegation.

Specifically, the elected species is directed to *primary* pulmonary hypertension which is art recognized to have an unknown etiology (see, for example, page 2, paragraph [0008] of the specification as well as at the pages printed from the following web site on June 9, 2006 www.primary-pulmonary-hypertension-pph.comp/pages/whatispph.html). The simple fact that primary pulmonary hypertension is a disease of unknown etiology is supported by the Declaration of Dr. Eldon Raymond Smith, attached hereto. Dr. Smith states, in part, that:

Primary pulmonary hypertension (PPH) is a disease of the pulmonary arteries of unknown etiology, affecting mostly younger people and more often women.

In contrast, *secondary* pulmonary hypertension is a disease of known etiology (see, *e.g.*, www.primary-pulmonary-hypertension-pph.comp/pages/whatispph.html), which recites that if

the pulmonary hypertension develops as the result of (*i.e.* secondary to) another disease, thereby having a known etiology, it is classified as secondary pulmonary hypertension. Again, this is supported by the Declaration of Dr. Eldon Raymond Smith, which states

Pulmonary hypertension can also be secondary, particularly developing because of left heart disease leading to congestive heart failure.

Finally, the physiological effects of primary and secondary pulmonary hypertension are different. As stated by Dr. Smith in his Declaration,

Moreover, there are characteristic pathologic changes in the pulmonary arterial wall in PPH which are not observed when pulmonary hypertension develops secondary to left ventricular disease leading to congestive heart failure. As such, PPH and pulmonary hypertension which develops secondary to congestive heart failure are different conditions with different etiologies. Moreover, some of the treatments that have proven effective in secondary pulmonary hypertension are not effective (and occasionally may worse) primary pulmonary hypertension.

As noted by the Examiner, the cited Smith reference fails to teach treating primary pulmonary hypertension. The cited Sakai reference specifically recites in the last paragraph of the Abstract that the pulmonary hypertension treated therein is caused by CHF – that is to say that it is pulmonary hypertension that develops secondary to congestive heart failure. Nothing in Smith nor Sakai suggest treating primary pulmonary hypertension. Moreover, since by definition primary pulmonary hypertension is of unknown etiology, logic dictates that the this pulmonary hypertension cannot be caused by CHF, otherwise it would not be termed “primary”.

As the underlying premise for this rejection is wrong, this rejection is in error. Withdrawal of this rejection is requested.

The Examiner is requested to contact the undersigned by telephone if a personal interview is deemed appropriate.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

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REPLACEMENT SHEET
(CLEAN COPY ALSO ENCLOSED)

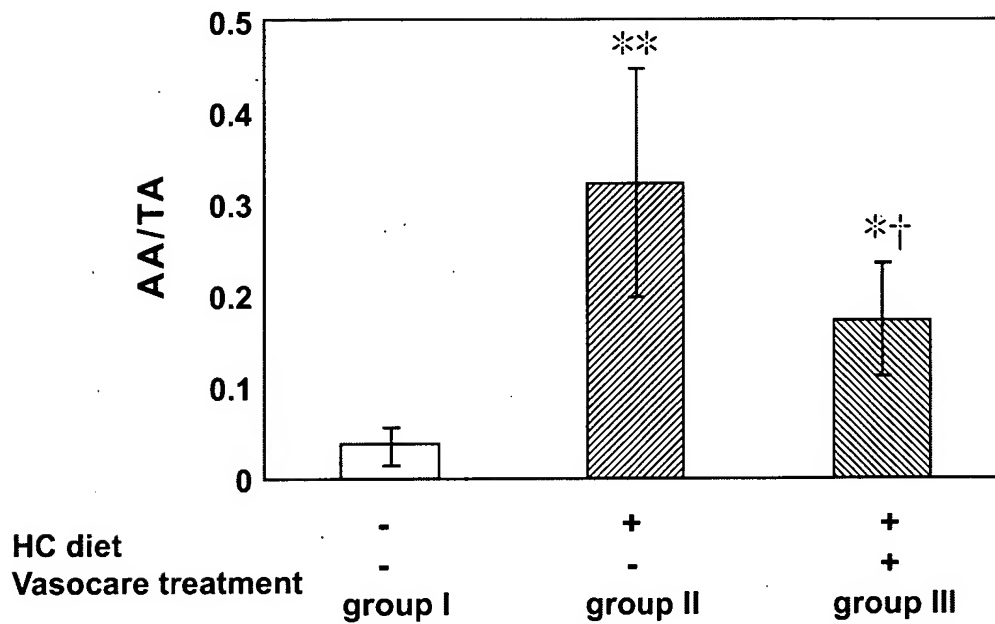


FIG. 1